# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/508,635 | 05/18/2000 | OLIVIER BALLEVRE | P00.0164 | 7617 |

29157 7590 11/15/2005

BELL, BOYD & LLOYD LLC
P. O. BOX 1135
CHICAGO, IL 60690-1135

| EXAMINER | |
|---|---|
| LUKTON, DAVID | |
| **ART UNIT** | **PAPER NUMBER** |
| 1654 | |

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/508,635 | BALLEVRE ET AL. | |
| | Examiner | Art Unit | |
| | David Lukton | 1654 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *8/26/05*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *30,32,35 and 37-41* is/are pending in the application.

4a) Of the above claim(s) *33 and 34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30,32,35 and 37-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/26/05 has been entered.

✦

Pursuant to the directives of the amendment filed 7/8/05 claim 30 has been amended. Claims 30, 32-35 and 37-41 remain pending. Claims 33-34 remain withdrawn from consideration. Applicants' arguments filed 7/8/05 have been considered and found persuasive in part.

The rejection of claims 30, 32, 35 and 37-41 as unpatentable over Tomita ('873) is withdrawn.

✦

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the claimed invention.

Claim 30 now recites that the organ for which recovery is to be promoted has to be an "internal organ". As it happens, there is no literal support for the term "internal organ". Applicants are attempting to carve out a genus which was not described. Further, there is some ambiguity regarding the dividing line between internal organs and external ones. In applicants' opinion, are the eyes external organs, or internal ones? What about the female breast or the male genitalia? Are the ears of an elephant internal organs or external ones? And even where the skin is concerned, there is ambiguity. Certainly, the outer layers of the skin that are clearly visible would qualify as part of an external organ. But there are many layers to the skin. Where is the dividing line between skin that is part of an internal organ versus an external one? In applicants' opinion, is the stratified squamous epithelium internal or external? Is the stratum spinosum internal or external?

In addition to the foregoing, there is no description of "internal administration". It is true that on page 9, lines 6-7, the following passage is recited:

> "The nutritional formula may also be administered continuously by means of nasogastric tubes or enteral tubes...".

However, this does not provide support for "internal administration", or even parenteral administration. Nor is it clear, even at this point, what exactly is encompassed by "internal administration", or why it is that applicants believe that food which passes through the esophagus is somehow not present "internally".

✦

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification fails to teach a skilled physiologist how to use protein hydrolyzates and amino acids to promote "recovery" of an organ. As stated in *Ex parte Forman* (230 USPQ 546, 1986) and *In re Wands* (8 USPQ2d 1400, Fed. Cir., 1988), the factors to consider in evaluating the need (or absence of need) for "undue experimentation" are the following: quantity of experimentation necessary, amount of direction or guidance presented, presence or absence of working examples, nature of the invention, state of the prior art, relative skill of those in that art, predictability or unpredictability of the art, and breadth of the claims.

As for the "nature of the invention", it is asserted in the specification (page 8, line 17+) that the disclosed protein hydrolyzates can be used to repair damage to the intestine. Also asserted (page 8, line 20+) is that the disclosed protein hydrolyzates can be used to treat Crohn's disease, diarrhea, colitis or sepsis, and further, that the disclosed protein hydrolyzates can be used to reverse damage to gut epithelial tissue that has resulted from a surgical procedure, or from any other cause. Though not specifically stated, the implication is that various diseases such as hepatitis, cirrhosis of the liver, and kidney infection can be successfully treated. Such diseases cause damage to organ tissue, and if the claimed

method is to be effective, the protein hydrolyzates must be effective not only to accelerate wound healing, but overcome the pathological basis of the organ damage. Applicants have argued that while the term "recovery of an organ" is intended to encompass Crohn's disease, diarrhea, colitis and sepsis, the skilled artisan reading the specification would come to believe that hepatitis, cirrhosis of the liver, and kidney infection are all excluded. However, the reasons for such a conclusion are not provided by applicants. If "recovery of an organ" can encompass treatment of Crohn's disease, diarrhea, colitis and sepsis, it stands to reason that other diseases which affect organs would be encompassed as well. Furthermore, the skilled microbiologist would expect that many organs of the septic patient would be affected, not just the bowel.

As for the "working examples", the specification discloses results which are consistent with the conclusion that if one administers a mixture of all 20 genetically encoded amino acids to a mammal, the relative weights of the stomach, intestine, duodenum jejunum, liver, gastrocnemius, soleus, and extensor will vary slightly if the ratio of amino acids is altered. This assertion is somewhat suspect, since no statistical analysis has been presented. For example, in the case of the duodenum, the standard deviation would not have to be high at all in order to justify the conclusion that the results are not statistically significant. Without further information as to the variability in the data (that is presented on page 17), it is not particularly meaningful. The results are also not meaningful, since the amount of lipids and minerals (see page 14) were varied simultaneously with the amino acid

composition. Furthermore, the total amount of amino acids varies from from feed mixture to the next. Thus, even if it turns out that the results on page 17 are statistically significant, it has not been determined the extent to which, or even whether, the observed changes in organ weights were the result of varying the amino acid composition, rather than the lipids and minerals. It may be the case that the changes in organ weights were due to changes in the total amount of amino acids administered, rather than variations in the amino acid content. Or maybe the changes in organ weights were due to changes in differential metabolism of the peptide fragments which were produced by the different hydrolysis methods (hydrolyzate 1, hydrolyzate 2 or hydrolyzate 3). Thus, in the disclosed experiments (specification) several different variables have been altered simultaneously, and it is impossible to determine the effects of any one of them taken alone. Furthermore, there is no control experiment. It has not been stated what the results are supposed to be relative to. If the feed compositions (feed 1 - feed 5) were given to rats which were already exhibiting a positive nitrogen balance, would there be any effect at all of the different feeds?

Even if it turns out that the results on page 17 are statistically significant, and if could be determined what the cause (among the numerous variables) of the variance in organ weights might be, the results are still not meaningful with respect to the claimed invention. The claimed invention is not drawn to a method of randomly altering the weights of selected organs. And even if the claims were drawn e.g., to a method of increasing the weight of the stomach, it is not at all clear how one would proceed. It may be true that if one uses,

e.g., feed #5 rather than feed #1, one will obtain a slightly higher weight of the stomach. If it were to turn out that this difference is due to the amino acid content, rather than to the lipids and minerals (or one of the other variables), it would still not be evident how one would translate the results of feed #5 versus feed #1 into a general method of increasing stomach weight. It is not apparent which amino acids are necessary, or which are sufficient; it is not made clear ~~wat~~ what degree of hydrolysis will produce the intended results, and which will not. And even if it were true that the specification taught the skilled artisan how to increase the weight of specific organs, there is no teaching as to how that teaching would translate into a showing of enablement for the claimed invention, which is that of using protein hydrolyzates and amino acids to promote "recovery" of an organ.

The results of a second experiment are presented on pages 21-24. What is shown here is that the rate of protein synthesis varies somewhat depending on which of the five feeds is used. The shortcomings of the experimental results described on page 17 apply here as well. First, the results are not statistically significant in the absence of further information as to the variability that is observed from one experiment to the next (for a given feed composition). Second, there are several different variables (with respect to the feed composition itself) which are altered simultaneously. And third, even if there were a clear assertion as to the specific variable that is supposed to correlate with the increased protein synthesis, and even if there were an experimental basis for such an assertion, this would have little relevance to the claimed invention, which is that of using protein hydrolyzates

and amino acids to promote "recovery" of an organ. The specification has presented no evidence that any such correlation exists between rate of protein synthesis, and recovery of an organ from wounding, physical trauma, or damage from an inflammatory condition. The reality is that one cannot "predict" such "recovery" based on rates of protein synthesis.

The following references discusses the issue of statistical analysis, and more importantly the issue of artifacts or invalid conclusions that can be drawn from an inadequate experimental design, or flawed assumption:

Ludbrook (*Clinical and Experimental Pharmacology and Physiology* 28 (5-6) 488-92, 2001)

Bryant (*Pediatric Allergy and Immunology* 9 (3) 108-15, 1998)

Bezeau (*Journal of Clinical and Experimental Neuropsychology* 23 (3) 399-406, 2001)

Bolton (*Journal of Clinical Pharmacology* 38 (5) 408-12, 1998)

Willenheimer (*Progress in Cardiovascular Diseases* 44 (3) 155-67, 2001)

Chung (*Plastic and Reconstructive Surgery* 109 (1) 1-6, 2002)

Atkinson (Chronobiology International 18 (6) 1041-53, 2001).

While several experiments have been conducted, there is no apparent relationship between the results of those experiments, and the claimed invention. The claimed invention encompasses repair of damage to the intestines, treatment of Crohn's disease, treatment of diarrhea, treatment of colitis or sepsis, treatment of hepatitis, treatment of cirrhosis of the

liver, and kidney infection, as well as reversal of damage to gut epithelial tissue. There is no evidence that increasing DNA synthesis or even increasing organ weight engenders a method of promoting wound healing, or of successfully treating a patient whose organs have been damaged by disease, surgery or trauma. "Undue experimentation" would be required to practice the claimed invention.

In response to the foregoing, applicants have argued that the term "recovery" is definite in scope and meaning. However, even if this is true, it does not follow therefrom that the skilled artisan can predict repair of damage to the intestines, treatment of Crohn's disease, treatment of diarrhea, treatment of colitis or sepsis, treatment of hepatitis, treatment of cirrhosis of the liver, and kidney infection, as well as reversal of damage to gut epithelial tissue on the basis of increased protein or DNA synthesis.

The rejection is maintained.

✦

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to a method of promoting "recovery" of an organ. It is unclear as to what the organ is recovering from. The term could potentially encompass recovery from a wound, physical trauma, or a disease. Despite the amendment, the line between what is encompassed and what is not encompassed remains unclear. For example, one organ is the brain. Is "recovery" from a headache encompassed, or recovery from emotional stress, or recovery from excessive alcohol consumption? It is suggested that the claim be amended to make clear what the mammal is recovering from.

✦

The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Nakamura (*J. Dairy Sci.* **78** (6) 1253-1257, 1995) or Masuda (*American Institute of Nutrition* **126**(12) 3063-3068, 1996).

As indicated previously, Nakamura discloses that peptides obtained from sour milk exhibit antihypertensive activity. Nakamura does not disclose that antihypertensive agents will promote "recovery" of a damaged heart in hypertensive patients. Masuda provides a similar teaching. Applicants have argued that neither reference discloses that antihypertensive agents are often prescribed for hypertensive patients how have suffered a

heart attack. However, this is well known in the art. The rejection is maintained.

✧

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Nakamura (*J. Dairy Sci.* **78** (6) 1253-1257, 1995) in view of Ichikawa (USP 5,071,867) or Masuda (*American Institute of Nutrition* **126**(12) 3063-3068, 1996) in view of Ichikawa ('867) .

As indicated previously, Nakamura discloses that peptides obtained from sour milk exhibit antihypertensive activity. Masuda provides a similar teaching. Neither reference discloses that antihypertensive agents promote "recovery" of kidneys. Ichikawa discloses (e.g., col 1, line 21+) that antihypertensive agents promote "recovery" of kidneys. Ichikawa does not disclose administration of milk protein hydrolyzates.

Thus, the nephrologist of ordinary skill would recognize that the milk protein hydrolyzates of Nakamura and of Masuda will be effective to promote recovery of kidneys.

✧

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Gordon (USP 5,166,132).

As indicated previously, Gordon teaches that milk protein hydrolyzates can be used to treat skin, which is an organ.

Applicants have argued that the amendment to claim 30 overcomes this rejection.

However, Gordon also teaches (e.g., col 6, line 36) that the milk protein hydrolyzates can be used to treat vascular tumors or arthritis. The first point is that the medical specialist of ordinary skill would have had motivation to administer the composition subcutaneously or systemically. But in addition, there is the matter of transdermal administration. This form of administration is well known in the art. The point is that in order for the compositions of Gordon to be effective in the treatment of vascular tumors and arthritis, at least a portion of that composition would have to reach an anatomical location which would qualify as an "internal" site.

The rejection is maintained.

✦

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Gordon (USP 5,166,132) in view of Verma (USP 6,645,942). The teachings of Gordon are indicated above. Gordan does not teach that skin is an organ. Verma discloses (col 4, line 47) that skin is an organ. Verma does not disclose the use of milk protein hydrolyzates to promote recovery of an organ.

The rejection is maintained.

✦

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Smith (WO 97/16460).

As indicated previously, Smith discloses that a casein hydrolyzate has growth promoting activity. Smith does not explicitly state that the casein hydrolyzate will promote "recovery of an organ". However, one of ordinary skill would expect that growth of organs will be promoted, those of infants, as well as those of adults who have suffered damage to an organ as a result of disease, injury or surgical procedure.

In response to the foregoing, applicants have argued that Smith does not disclose "specific" organ recovery. However, given that the casein hydrolyzate has growth promoting activity, one of ordinary skill would expect that the hydrolyzate will help repair damaged organs. If at least one damaged organ is repaired, then that organ qualifies as a "specific" one.

Applicants have also argued that Smith does not disclose that the degree of absorption varies with the degree of hydrolysis. While this may be true, the claims do not require such.

The rejection is maintained.

✦

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Jolles (USP 4,716,151).

As indicated previously, Jolles discloses that tripeptides obtained from hydrolysis of milk proteins will stimulate the immune system. Jolles does not disclose that the recited tripeptides will promote recovery of an organ in an immune compromised patient.

Applicants have argued that the immunostimulatory effect is general, and one would not expect that recovery of a "specific" organ will be achieved. However, the term "specific" in the context of claim 30, is not particulary meaningful. There is not a single internal organ which is excluded by claim 30. Claim 30 encompasses the possibility that recovery of each and every internal organ can occur simultaneously, or just one of them. In the case of Jolles, one would expect that if a "specific" organ were infected with bacteria or viruses or fungi, that the tripeptides will promote recovery of that organ. As a practical matter, it is rarely the case that each and every organ becomes infected simultaneously, and to the same degree. The typical case is one in which a single organ, or perhaps two organs become infected. For such a case, recovery of the organ will be specific.

The rejection is maintained.

✦

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Ballard (USP 5,679,771) in view of Stalker (USP 5,661,123).

Ballard discloses (e.g., col 2, line 6+; col 2, line 26+; col 1, line 30+) recovery from Crohn's disease and colitis, and recovery from surgical procedures by administering IGF-1 and analogs thereof. Ballard does not disclose a method of promoting recovery by administering hydrolyzed milk proteins. Stalker discloses (col 3, line 50) administration of hydrolyzed milk proteins to patients who have "elevated protein requirements". Stalker further discloses (e.g., col 3, line 40; col 5, line 47) that persons

afflicted with Crohn's disease have "elevated protein requirements" and would benefit from the hydrolyzed milk proteins. While disclosing that persons suffering from Crohn's disease would benefit from the hydrolyzed milk proteins, Stalker stops short of asserting that the inflammation associated with the Crohn's disease will actually be mitigated.

In response to the foregoing, applicants have argued that the instant claims require recovery of a "specific" organ, as opposed to a "general" organ. However, the term "specific" in the context of claim 30, is not particulary meaningful. There is not a single internal organ which is excluded by claim 30. Claim 30 encompasses the possibility that recovery of each and every internal organ can occur simultaneously, or just one of them. Thus, for all practical purposes, the claims do not actually require that recovery occur in just one particular organ (or three organs). But as it happens, this rejection is directed especially to promoting recovery in patients who are suffering from Crohn's disease. The bowel is the organ preferred by applicants in which to promote recovery. The references taken together teach this.

Applicants have also argued that Stalker does not disclose that the degree of absorption varies with the degree of hydrolysis. While this may be true, the claims do not require such.

The rejection is maintained.

✦

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Qu, Zhensheng (*Journal of Nutrition* **126**(4) 906-912, 1996) in view of Stalker (USP 5,661,123).

As indicated previously, Qu discloses that protein malnutrition is manifest in various ways both biochemically and physiologically; one of those manifestations is suboptimal liver growth. Qu further discloses that the deficiency in liver growth which accompanies protein malnutrition can be reversed by administering proteins, such as casein; in other words, proteins promote "recovery" of the liver from protein malnutrition. Qu does not disclose that hydrolyzed milk proteins can serve as a protein source.

Applicants have argued that Stalker does not disclose that varying the degree of hydrolysis has the effect of altering the extent to which benefit accrues to one specific organ versus another. While applicants may be correct on this point, the claims are not drawn to a method of varying the degree of hydrolysis, or a Jepson claim in which the improvement is varying the degree of hydrolysis. The rejection is maintained.

✦

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Gray (USP 5,723,446).

Gray discloses (col 2, line 57+) a method of treating patients suffering from burns, and from surgical procedures. The method calls (col 3, line 27) for administration of

hydrolyzed milk protein.

In response, applicants have argued that Gray does not disclose that varying the degree of hydrolysis has the effect of altering the extent to which benefit accrues to one specific organ versus another. While applicants may be correct on this point, the claims are not drawn to a method of varying the degree of hydrolysis, or a Jepson claim in which the improvement is varying the degree of hydrolysis. The rejection is maintained.

✧

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Gray (USP 5,723,446) in view of Van Leeuwen (USP 6,001,878).

Gray discloses (col 2, line 57+) a method of treating patients suffering from burns, and from surgical procedures. The method calls (col 3, line 27) for administration of hydrolyzed milk protein. The reference also suggests (col 3, line 47; col 5, line 56) administration of glutamine in addition to the hydrolyzed milk protein. Gray does not disclose that glutamine will promote recovery of an organ. Van Leeuwen discloses that glutamine will promote recovery of the liver. Van Leeuwen does not disclose administration of hydrolyzed milk proteins.

In response, applicants have argued that Gray does not disclose that varying the degree of hydrolysis has the effect of altering the extent to which benefit accrues to one specific organ versus another. While applicants may be correct on this point, the claims are not drawn to a method of varying the degree of hydrolysis, or a Jepson claim in which the

improvement is varying the degree of hydrolysis. The rejection is maintained.

✦

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Gray (USP 5,723,446) in view of Panigrahi (USP 5,981,590).

Gray discloses (col 2, line 57+) a method of treating patients suffering from burns, and from surgical procedures. The method calls (col 3, line 27) for administration of hydrolyzed milk protein. The reference also suggests (col 3, line 47; col 5, line 56) administration of glutamine in addition to the hydrolyzed milk protein. Gray does not disclose that glutamine will promote recovery of an organ. Panigrahi discloses that glutamine will promote recovery of the intestines. Panigrahi does not disclose administration of hydrolyzed milk proteins.

In response, applicants have argued that Gray does not disclose that varying the degree of hydrolysis has the effect of altering the extent to which benefit accrues to one specific organ versus another. While applicants may be correct on this point, the claims are not drawn to a method of varying the degree of hydrolysis, or a Jepson claim in which the improvement is varying the degree of hydrolysis. The rejection is maintained.

✦

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Boza, Julio (*Journal of Pediatric Gastroenterology and Nutrition* **22**(2) 186-193, 1996).

Boza discloses that the weight and protein content of the jejunum mucosa is reduced following starvation, and that the hydrolase activity of the mucosa also is also reduced in starvation. Boza also discloses that these effects of starvation are reversed following administration of hydrolyzed milk proteins. Boza does not disclose that administration of hydrolyzed milk proteins will promote recovery of an organ.

In response, applicants have argued that Boza does not disclose that varying the degree of hydrolysis has the effect of altering the extent to which benefit accrues to one specific organ versus another. While applicants may be correct on this point, the claims are not drawn to a method of varying the degree of hydrolysis, or a Jepson claim in which the improvement is varying the degree of hydrolysis.

Applicants have also argued that Boza teaches only recovery of organs in subjects which have been subject to starvation. While this may be true, there is nothing in the instant claims to exclude this embodiment. The instant claims impose no limitations on the cause of the damage to the organs (which damage one is endeavoring to reverse).

Applicants have also argued that the degree of hydrolysis of the Boza hydrolyzates is not "pre determined". However, applicants have provided no evidence that this is the case, or even provided an argument as to what physical characteristics distinguish a hydrolyzate that has a "predetermined" degree of hydrolysis from a hydrolyzate in which the degree of hydrolysis is not "predetermined".

The rejection is maintained.

✦

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at (571)272-0974. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

DAVID LUKTON
PATENT EXAMINER
GROUP 1800